



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

AUG 3 1988

MEMORANDUM

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

SUBJECT: Administrative Clarification of FIFRA and FFDCA
Redelegations of Authority - ACTION MEMORANDUM

FROM: Douglas Camp, Director
Office of Pesticide Programs

TO: John A. Moore
Assistant Administrator
for Pesticides
and Toxic Substances

ISSUE

To approve administrative clarification to redelegations of authority under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug, and Cosmetic Act (FFDCA).

BACKGROUND

The Office of Pesticide Programs (OPP) and the Office of General Counsel (OGC) propose that the Assistant Administrator for Pesticides and Toxic Substances (AAOPTS) affirm the redelegation of authority from the AAOPTS to the Director of OPP for fourteen Delegations of Authority (attached) concerning pesticide regulation. OPP and OGC believe that this will reduce confusion by identifying correctly and publicly, in one action, the authorities that were redelegated in fact to the Director of OPP several years ago through a series of actions and formal reorganizations. This action does not involve any revision of the existing levels of redelegation.

RECOMMENDATION

That you sign below to affirm the redelegation of authority to the Director of OPP for the following Delegations: FIFRA 5-1A, 5-1B, 5-1C, 5-3, 5-5, 5-7, 5-16, 5-20, 5-22, 5-24, 5-26, 5-29, 5-31; FFDCA 6-1, 6-2, 6-3.

Approve

Disapprove

Date

Attachment



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OCT 23 1995

OFFICE OF
PREVENTION, PESTICIDES, AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Delegation of Authority to Biopesticides and Pollution Prevention Division

FROM: Daniel M. Barolo, Director
Office of Pesticide Programs

TO: Lois Rossi, Director
Special Review and Reregistration Division

Stephen L. Johnson, Director
Registration Division

Janet Andersen, Director
Biopesticides and Pollution Prevention Division

The purpose of this memorandum is to modify existing delegations of authority to permanently include the Director, Biopesticides and Pollution Prevention Division (BPPD). In November of last year, I issued temporary delegations of authority to BPPD that expired on September 30, 1995, at the completion of the pilot. As of October 1, 1995, BPPD is a permanent OPP division. Therefore, with this memo, I convert the temporary delegations of authority to permanent.

The following modified delegations are included in this package:

1. 5-1A. New Chemical Registrations
2. 5-1B. Change to Existing Registrations
3. 5-3. Issuance of Experimental Use Permits
4. 6-2B. Prescribing Tolerances for Pesticides
5. 6-3B. Prescribing Tolerances for Pesticides

Attachments

cc: Lynn Goldman
Susan Wayland
Jim Aidala
Angela Hoffman
OPP Division Directors
PSPS Director
Artie Williams, OPP Delegations Workgroup
Kevin Lee, OGC

DELEGATIONS MANUAL

FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT (FIFRA)

5-1A. NEW CHEMICAL REGISTRATION

1. AUTHORITY. To perform the EPA functions and responsibilities relative to the registration of pesticides pursuant to Section 3 of FIFRA, as amended, including, but not limited to, the authority:
 - a. To register new pesticide products;
 - b. To deny registration for a new pesticide product based upon the failure of an applicant to submit required information or to follow other required procedures;
 - c. To make available to the public, upon registration, the data required in the registration statement pursuant to Section 3(c)(2), as limited by Section 3(c)(1)(D) and Section 10;
 - d. To classify uses of pesticide products for general or restricted use pursuant to Section 3(d)(1);
 - e. To determine whether a substance is a pesticide or a device subject to the requirements of FIFRA;
 - f. To determine the acceptability of data for registration, to request additional data, to waive data requirements where significant regulatory or environmental impact is not involved, and to determine the acceptability of labeling;
 - g. To determine whether an application for registration involves a changed use pattern; and
 - h. To publish notice of application for a product containing any new active ingredient or involving a changed use pattern pursuant to Section 3(c)(4).
2. TO WHOM DELEGATED. Division Director, Biopesticides and Pollution Prevention Division, and Branch Chiefs, Registration Division, Office of Pesticide Programs.
3. LIMITATIONS.
 - a. The authority to publish guidelines specifying information requirements in support of registration as set forth in Section 3(c)(2) is reserved to the Administrator.

- b. Authority to approve registrations of pesticides containing active ingredients or for uses identical or similar to those finally canceled by an order of the Administrator is reserved to the Administrator.
 - c. Authority to issue Federal Register rulemaking documents under the amended FIFRA is reserved to the Administrator and the Assistant Administrator OPPTS.
 - d. Authority to deny the registration of a pesticide under Section 3(c)(6) for substantive reasons, including but not limited to reasons other than the failure of an applicant to submit required information or to follow required procedures is reserved to the Director, OPP.
 - e. Authority to change the classification of a use of a pesticide under section 3(d)(2) is reserved to the Director, OPP.
 - f. Authority to grant or deny a data waiver request, which involves a claim that certain data requirements should not be applied to a group of products because of a common characteristic of the products (e.g., low volume products) which makes the data inappropriate, is reserved to the Director, OPP.
 - g. Authority to waive a data requirement involving significant regulatory or environmental impact is reserved to the Director, OPP. Data requirements involving significant impact include, but are not limited to, those which involve classes of products (because of their physical form or mode of action) or involve chemical standards for active ingredients or formulations of products.
 - h. Authority to waive a data requirement for which an identical or substantially similar waiver has previously been granted may be redelegated below the Division Director level. No other authority to waive a data requirement may be redelegated below the Division Director level.
 - i. Authority to sign Federal Register Documents may not be delegated below the Division Director level.
4. REDELEGATION OF AUTHORITY. Authorities to classify uses of pesticide products for general or restricted use pursuant to Section 3(d)(1) and to determine whether a substance is a pesticide or a device subject to the requirements of FIFRA may not be delegated below Branch Chief level. Authority to register new pesticide products (with concurrence from the Division Director) may be redelegated. All other authorities not prohibited may be redelegated.

DELEGATIONS MANUAL

FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT (FIFRA)

5-1B. CHANGE TO EXISTING REGISTRATION

1. AUTHORITY. To perform the EPA functions and responsibilities relative to the amending of existing registrations and the approval of new uses for existing registrations of pesticides pursuant to Section 3 of FIFRA, as amended, including, but not limited to, the authority:
 - a) To approve or deny amendments to currently registered products;
 - b) To continue or cancel the registration of a product pursuant to 40 CFR 162.6(c), five year cancellation;
 - c) To make available to the public the data required in the registration statement pursuant to Section 3(c)(2), as limited by Section 3(c)(1)(D) and Section 10;
 - d) To classify uses of pesticide products for general or restricted use pursuant to Section 3(d)(1);
 - e) To determine whether a substance is a pesticide or a device subject to the requirements of FIFRA;
 - f) To determine the acceptability of data for registration, to request additional data, to waive data requirements where significant regulatory or environmental impact is not involved, and to determine the acceptability of labeling;
 - g) To determine whether an application for amendment involves a changed use pattern;
 - h) To publish notice of application for a product containing any new active ingredient or involving a changed use pattern pursuant to Section 3(c)(4); and
 - i) To issue notices of intent to suspend (including the establishment of existing stock provisions), to rescind such notices, and to reinstate suspended registration, as appropriate, pursuant to Section 3(c)(2)(B)(iv).
2. TO WHOM DELEGATED. Directors, Registration Division, Special Review and Reregistration Division, and Biopesticides and Pollution Prevention Division. The Registration Division and Biopesticides and Pollution Prevention Division shall exercise all authority that is not reserved under the limitations. The Special Review and Reregistration Division may exercise authority to: classify

products as general or restricted use, issue data call-in notices, issue and rescind notices of intent to suspend under FIFRA Section 3(c)(2)(B).

3. LIMITATIONS.

- a) Authority to publish guidelines specifying information requirements in support of registration as set forth in Section 3(c)(2) is reserved to the Administrator.
- b) The authority to approve registrations of pesticides containing active ingredients or for uses identical or similar to those finally canceled by an order of the Administrator is reserved to the Administrator.
- c) Authority to issue Federal Register rulemaking documents under the amended FIFRA is reserved to the Administrator and the Assistant Administrator, OPPTS.
- d) Authority to deny the registration of a pesticide under Section 3(c)(6) for substantive reasons, including but not limited to reasons other than the failure of an applicant to submit required information or to follow required procedures is reserved to the Director, OPP.
- e) Authority to change the classification of a use of a pesticide under Section 3(d)(2) is reserved to the Director, OPP.
- f) Authority to waive a data requirement involving significant regulatory or environmental impact is reserved to the Director, OPP. Data requirements involving significant impact include, but are not limited to, those which involve classes of products (because of their physical form or mode of action) or involve chemical standards for active ingredients or formulations of products.
- g) Authority to grant or deny a data waiver request, which involves a claim that certain data requirements should not be applied to a group of products because of a common characteristic of the products (e.g., low volume products) which makes the data inappropriate, is reserved to the Director, OPP.
- h) Authority to issue a notice of intent to initiate a special review (40 CFR 154.21), or a notice indicating a decision not to begin a special review (40 CFR 154.23) after having given notice under 40 CFR 154.21 is reserved to the Director, OPP.
- i) Authority to waive a data requirement for which an identical or substantially similar waiver has previously been granted may be redelegated below the Division Director level. No other authority to waive a data requirement may be redelegated below the Division

Director level.

- j) Each Division Director shall exercise the delegated authority only in those cases which are within the jurisdiction of the Division Director. Any significant question as to which Division Director may exercise this authority in a given case should be referred to the Director, OPP, for resolution.
4. REDELEGATION OF AUTHORITY. Authority to sign Federal Register Notices is delegated to the same official to whom decision authority is granted unless specifically not delegated as indicated in the limitations. However, authority to sign Federal Register Documents may not be delegated below the Division Director level. All other authorities not previously reserved may be redelegated.



DELEGATIONS MANUAL

FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT (FIFRA)

5-3. ISSUANCE OF EXPERIMENTAL USE PERMITS

1. AUTHORITY. To perform the EPA functions and responsibilities relative to the issuance of Experimental Use Permits, pursuant to Section 5(a), (b), (c), (d), and (g) of FIFRA, as amended, including, but not limited to, the authority:
 - a) To issue or deny an experimental use permit for use on acreage that does not exceed 5000 acres;
 - b) To prescribe the terms, conditions, and time period for each permit; and
 - c) To require studies of the effect on the environment of chemicals or chemical combinations contained in a pesticide for which an Experimental Use Permit has been issued.
2. TO WHOM DELEGATED. Directors, Registration Division and Biopesticides and Pollution Prevention Division.
3. LIMITATIONS.
 - a) The authority to promulgate regulations governing the Experimental Use Permit program is reserved to the Administrator.
 - b) Issuance of permits for active ingredients and uses previously canceled by final order of the Administrator on grounds of unreasonable adverse effects is reserved to the Assistant Administrator for Prevention, Pesticides, and Toxic Substances or the Administrator as items of major national importance.
 - c) Issuance of experimental use permits for pesticides use on 5,000 acres or more is reserved to the Director, OPP.
4. REDELEGATION OF AUTHORITY. Authority to sign FR Notices is delegated to the same official to whom decision authority is granted, unless restricted in the limitations. Authority to sign FR documents may not be delegated below the Division Director level. All other authorities not previously reserved may be redelegated.

DELEGATIONS MANUAL

FEDERAL FOOD, DRUG AND COSMETIC ACT (FFDCA)

6-2B. PRESCRIBING TOLERANCES FOR PESTICIDES

1. AUTHORITY. To perform the EPA functions and responsibilities relative to the prescription and revocation of tolerances or exemptions for pesticides in or on raw agricultural commodities, as set forth in FFDCA, Section 408.
2. TO WHOM DELEGATED. Directors, Registration Division, Special Review and Reregistration Division and Biopesticides and Pollution Prevention Division.
3. LIMITATIONS.
 - a) Establishment of the first tolerance or exemption from a tolerance for a chemical is reserved to the Office Director.
 - b) The Office Director will be briefed prior to establishment of revocation of a tolerance where substantial comments were received on the proposal.
 - c) Tolerance actions involving application, or possible application, of the Delaney Clause are reserved to the Office Director. These actions include any action to establish, revise, or revoke (a) a section 409 tolerance for a pesticide that has been found to "induce cancer" or to be a potential human carcinogen, and (b) a Section 408 tolerance for a pesticide which leaves residues that concentrate when a raw commodity is processed.
 - d) Consultation with the Office of General Counsel is required prior to an issuance or revocation of a tolerance or an exemption.
4. REDELEGATION OF AUTHORITY. Establishment, revision, or revocation of a tolerance or exemption from tolerance are reserved to the Directors, Registration Division, Special Review and Reregistration Division, and Biopesticides and Pollution Prevention Division. All other authorities not previously reserved may be redelegated.

DELEGATIONS MANUAL

FEDERAL FOOD, DRUG AND COSMETIC ACT (FFDCA)

6-3B. PRESCRIBING TOLERANCES FOR PESTICIDES

1. AUTHORITY. To perform the EPA functions and responsibilities relative to the prescription and revocation of food additive regulations and exemptions, as set forth in FFDCA, Section 409.
2. TO WHOM DELEGATED. Directors, Registration Division, Special Review and Reregistration Division, and Biopesticides and Pollution Prevention Division.
3. LIMITATIONS.
 - a) Establishment of the first tolerance or exemption from a tolerance for a chemical is reserved to the Office Director.
 - b) The Office Director will be briefed prior to establishment of revocation of a tolerance where substantial comments were received on the proposal.
 - c) Tolerance actions involving application, or possible application, of the Delaney Clause are reserved to the Office Director. These actions include any action to establish, revise, or revoke (a) a section 409 tolerance for a pesticide that has been found to "induce cancer" or to be a potential human carcinogen, and (b) a Section 408 tolerance for a pesticide which leaves residues that concentrate when a raw commodity is processed.
 - d) Consultation with the Office of General Counsel is required prior to an issuance or revocation of a tolerance or an exemption.
4. REDELEGATION OF AUTHORITY. Establishment, revision, or revocation of a tolerance or exemption from tolerance are reserved to the Directors, Registration Division, Special Review and Reregistration Division, and Biopesticides and Pollution Prevention Division. All other authorities not previously reserved may be redelegated.